

JUN 3 - 2005

510(k) Summary  
(As required by 21 CFR 807.92(a))

A. Submitter Information

Bioject Medical Technologies, Inc.  
20245 S.W. 95<sup>th</sup> Ave.  
Tualatin, OR 97062

Phone: 800-683-7221, ext. 4144  
Fax: 503-692-6698  
Email: [MTalbert@bioject.com](mailto:MTalbert@bioject.com)  
Contact: Melanie Talbert  
Director Product Development  
Date: March 18, 2005

B. Device Information

Trade/Proprietary Name:

cool.click®

Common Name:

Needle-Free Jet Injector

Classification Name:

Jet Injector, Non-Electrically Powered  
Fluid Injector

Predicate Device(s):

Clicker™ (cool.click®) K994384

Device Description:

Needle-Free Self Injection Device for  
Personal Use with Saizen® [somatropin  
(rDNA origin) for injection].  
Needle-Free Injector, Jet Injector

Intended Use:

Needle-Free Self Injection Device for  
Personal Use with Saizen® [somatropin  
(rDNA origin) for injection].

C. Comparison of Required Technological  
Characteristics:

This submission changes the labeling of the  
cool.click® to expand the indications for  
use to include adults in accordance with  
changes approved for Saizen® indications.

There are no significant changes in the  
device design or function.

D. Summary and Conclusion of  
Nonclinical and Clinical Tests:

No new nonclinical or clinical tests were conducted as part of this submission. Non clinical and clinical studies with Saizen® were conducted for the predicate cool.click submission K994384. The predicate submission included Saizen® pharmacokinetic and pharmacodynamic studies using the cool.click injector in adults demonstrating bioequivalence between needle and needle-free delivery of growth hormone.

Summary:

This submission describes the labeling changes associated with the changes to indications for use for the cool.click® Needle-Free Self Injection Device for Personal Use with Saizen®. Previously submitted nonclinical and clinical studies have demonstrated the bioequivalence between needle and cool.click® needle-free delivery of growth hormone.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Susan Frank, J.D.  
Director, Regulatory Affairs  
Bioject Medical Technologies, Incorporated  
20245 S.W. 95<sup>th</sup> Avenue  
Tualatin, Oregon 97062

Re: K050734  
Trade/Device Name: cool.click®  
Regulation Number: 21 CFR 880.5430  
Regulation Name: Nonelectrically Powered Fluid Injector  
Regulatory Class: II  
Product Code: KZE  
Dated: March 18, 2005  
Received: March 21, 2005

Dear Ms. Frank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

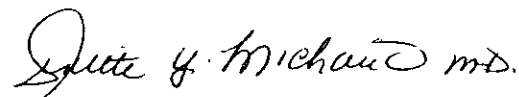
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number: ~~K~~050734

Device Name: cool.click®

Indications For Use: This product is indicated for Needle-Free Self Injection of Saizen® [somatotropin (rDNA origin) for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

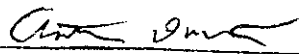
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number:   K050734